



# Welcome to the world of BioChem

COMPANY PRESENTATION



# BioChem analytical laboratory

- one of the leading German-based GMP-certified analytical contract laboratories
- 50 years of experience
- independent, family-owned
- located in Karlsruhe, Germany
- 4,100 m<sup>2</sup>, thereof 1,500 m<sup>2</sup> laboratory space
- expertise of more than 140 in-house specialists
- interdisciplinary competence, all from a single source:
  - microbiology
  - physico-chemical analytics
  - bioanalytics



# BioChem quality management



quality approved full-service provider:

- Manufacturer's Authorisation for:  
human medicinal products/human investigational med. products acc. to § 13 AMG  
veterinary medicinal products acc. to § 28 TAMG and (EU) 2019/6
- In-house QP (Qualified Person) acc. to § 15 AMG
- GMP-certified
- FDA-registered and repeatedly successfully inspected
- GLP-certified
- approx. 30-40 customer-based audits per year
- regular self-inspections



# BioChem further authorisations

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authorisation for ...

- handling of narcotics according to §3 BtmG
- handling of narcotic precursor according to GÜG and (EG) 273/2004 Art. 3 Abs. 2 of category 1 substances
- operation of genetic engineering facility according to GenTG and GenTAufzV as well as GenTSV of security level 1 and 2 according to GenTSV

BioChem has notified competent authorities about:

- handling of pathogenic organisms according to §§ 44 IfsG
- handling of epizootic disease germs according to TierSeuchErV



# BioChem analytical laboratory

- internationally active with customers all over Europe, USA, China, Japan, India, Singapore, Jordan, Saudi-Arabia, Israel, Mexico, Brazil, Canada
- focused on customers from the life science industry:
  - pharma
  - chemistry
  - medical devices
  - cosmetics
  - diagnostics





# BioChem business activities

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## quality control and development testing

- all dosage forms
- method development, transfer and validation
- identity, assay, purity and residue
- cleaning validation

## release and stability testing

- EU re-analysis
- storage according to ICH-guidelines

## GMP-/GLP-like documentation

- testing procedures, protocols and reports
- registration and submission support



# BioChem CORE COMPETENCIES



# MICROBIOLOGY

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Excerpt from our portfolio:

- microbial contamination testing (bioburden)
- identification of microorganisms
- sterility testing
- biological indicator testing
- bacterial endotoxin testing (LAL)
- assay of antibiotics
- efficacy of preservation testing
- on-site environmental monitoring
- non-routine testing and special testing for almost all microbiological questions

For more details, please contact our experts.

# PHYSICO-CHEMICAL ANALYTICS



Excerpt from our portfolio:

- physico-chemical testing
- chromatography
- spectroscopy/spectrometry
- determination of TOC/TN<sub>b</sub> (water analysis/cleaning validation)
- particle measurement
- elemental analysis
- dissolution testing
- photostability testing/stress tests
- stability studies (storage and testing)

For more details, please contact our experts.

# BIOANALYTICS



Excerpt from our portfolio:

- specializing on mAbs and Large Molecules
- determination of mycoplasma
- biological contamination testing
- determination of content and identity of nucleic acids
- determination of biological activity
- protein/antibody testing and determination of amino acids
- DNA/RNA testing
- identification of microorganisms (PCR), DNA-fingerprints
- bacterial endotoxin testing by rFC-test
- biotechnological product testing
- bioassays/cell-based assays/enzymatic tests

For more details, please contact our experts.

# Further services:

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## **Manufacturer's Authorisation for**

- for human medicinal products and human investigational medicinal products acc. to § 13 AMG and
- for veterinary medicinal products acc. to § 28 TAMG and (EU) 2019/6
- The manufacturing activities include the microbiological, chemical/physical and biological quality control testing of medicinal products, raw and starting materials, active pharmaceutical ingredients and packaging materials

## **QP service with in-house QP (Qualified Person acc. to § 15 AMG)**

- Confirmation of quality control by QP
- Storage of retention samples acc. to § 18 AMWHV and Annex 19 GMP guideline
- Consulting of clients on obtaining their own manufacturer's authorisation
- Further consulting services, e.g., on GMP topics and regulatory requirements on request

# For more details, please contact us

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